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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,956	07/11/2000	ROBERT ANDREW BADLEY	IMIN.P-019	6821

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EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/554,956	BADLEY ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-16 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-16, 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's response filed 6/22/04 is acknowledged and has been entered. Currently, claims 1-3, 5-16, and 22 are pending and are under examination.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 7-10, and 12-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Schramm (US Patent 5,281,539) for reasons of record in the Office Action mailed to Applicant on November 3, 2003.

3. Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US Patent 5,281,539) in view of Partin et al. (US Patent 5,082,630) for reasons of record in the Office Action mailed to Applicant on November 3, 2003.

4. Claims 5, 6, and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US Patent 5,281,539) in view of Presta et al. (US Patent 6,025,166) for reasons of record in the Office Action mailed to Applicant on November 3, 2003.

Response to Arguments

5. Applicant's arguments filed 6/22/04 have been fully considered but they are not persuasive.

A) Applicant argues that Schramm et al. fails to anticipate the claimed invention because it is not clear in Schramm how the captured moiety binding to the second surface meets the required limitation which states that, 1) "the capture moiety on the second surface generates a species capable of producing a detectable signal", and 2) "the signal cannot be generated unless and until the displacement moiety is captured on the second surface", since it is not clear how the signal is generated. Applicant specifically contends that the embodiment in Figure 7 uses Clark electrodes as sensors, which are oxygen electrodes, which would not directly detect anything that is bound to the sensor; hence, Applicant concludes that the Figure 7 embodiment in Schramm et al. is not enabling, since it does not describe how the signal is generated, and how the signal depends on the binding of the displaceable moiety to the surface of sensor 2.

In response, at column 8, lines 27-51 of the Schramm reference which explains Figure 7, it is provided that the presence of analyte causes a continuous displacement of displaceable moiety from Sensor 1 for capture of the displaceable moiety into Sensor 2, which results to continuous change of concentration of analyte in each individual sensor, and the change in concentration of analyte in each sensor including Sensor 2, is manifested as a measured signal. Hence, the displaceable moiety "species" generated in Sensor 2 is capable of producing its distinct detectable signal separate from that in Sensor 1, and the "[detectable, distinct] signal is not generated unless and until the

displacement moiety is captured on the second surface. Accordingly, the teaching of Schramm describing Figure 7 appears to read on claim 1.

In as far as use of Clark electrodes in Figure 7, Schramm intends such electrodes as only exemplary for certain embodiments, i.e. "sensors can be electrodes such as Clark electrodes", and does not intend such embodiment to limit the scope of his invention. Additionally, Schramm's disclosure of signal generating means for use in the method in column 4, lines 63-67, includes enzymes, fluorescent molecules, ultraviolet absorbent agents and other compounds capable of conjugation with the analyte, without deletion of the capacity to generate the signal. When using electrodes to detect the detectable signal, the analyte, if present, continually displaces the displaceable moiety and then is continually captured by the capture antibody so that the measured signal from the sensors each continuously and individually changes, with the concentration of the analyte captured on the sensor (see column 8, lines 27-62 and Figure 7). Accordingly, Applicant's argument that the disclosure of Schramm is not enabling for lack of description of how the signal is generated and how the signal depends on the binding of the displaceable moiety to the surface of Sensor 2, is not on point.

B) Applicant argues that the combination of Schramm with Partin is improper and does not render obvious the claimed invention. Applicant specifically contends that the embodiment of Figure 7 does not make use of fluorescence or other optical indicators; rather it uses an electrode in a manner that is not clearly disclosed.

Applicant argues that the mere fact that Schramm discloses optical signaling in other embodiments does not stand as a suggestion to use them in the embodiment of Figure 7, and then to modify them to further use the waveguide of Partin in the process.

In response, use of Clark electrodes in Figure 7 of Schramm is only intended as exemplary for certain embodiments, i.e. "sensors can be electrodes such as Clark electrodes", and does not intend such embodiment to limit the scope of his invention. Schramm discloses use of signal generating means in the method in column 4, lines 63-67, which includes enzymes, fluorescent molecules, ultraviolet absorbent agents and other compounds capable of conjugation with the analyte, without deletion of the capacity to generate the signal.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Schramm teaches contacting the first surface upon which a displaceable moiety such as an antibody or analyte has been reversibly bound, with a sample wherein analyte in the sample displaces the reversibly bound moiety causing the displaced moiety to bind to a second surface upon which a specific antibody is bound and detecting the signal which can be produced by fluorescence or enzyme

labels. Schramm teaches also using electrodes to detect the detectable signal, i.e. sensors, wherein the analyte, if present, continually displaces the displaceable moiety and then is continually captured by the capture antibody so that the measured signal from the sensors continuously changes, with the concentration of the analyte captured on the sensor. Partin is incorporated with the teaching of Schramm only for the teaching of a detectable signal generated by an evanescent or acoustic wave wherein if analyte is present in a sample, the analyte molecules displace some of the bound, fluorescent-tagged derivative, resulting in a decrease (modulation) in signal as detected by a detecting diode. The extent of the decrease is proportional to the concentration of the analyte. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to capture and detect the signal generated in the method of Schramm using the waveguide as taught by Partin because Schramm appears to be generic in the type of detection method used, depending on the labels used, and Partin taught that the optical fiber for use in detection has the advantage of being sensitive even at extremely low concentrations of analyte.

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
September 16, 2004 GG

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
9/15/04